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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,486	12/19/2000	Alan S. Waggoner	92053CONCIPCON	6161
23117	7590	01/23/2004	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			PONNALURI, PADMA SHRI	
			ART UNIT	PAPER NUMBER
			1639	26

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/740,486

Applicant(s)

WAGGONER, ALAN S.

Examiner

Padmashri Ponnaluri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/25/03, 11/7/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-12, 15, 19 and 21-29 is/are pending in the application.
- 4a) Of the above claim(s) 9-12, 15, 19 and 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 23.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed on 9/25/03, and the supplemental amendment filed on 11/7/03 have been fully considered and entered into the application.

Status of claims

2. Claims 1-8, 13-14, 16-18, 20 have been canceled, and claims 9-12, 15, 19 and 21-24 have been withdrawn from consideration, and claims 9-12, 15, 19, 21-29 are currently pending in this application..

3. This application contains claims 9-12, 21-24 (non-elected invention), and claims 15, 19 (non-elected species) drawn to an invention nonelected without traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

4. Claims 25-29 are currently being examined in this application.

Information Disclosure Statement

5. The reference by Neblette in the information disclosure statement filed on 9/25/03 fails to comply with the provisions of 37 CAR 1.97, 1.98 and MPEP § 609 because Neblette reference does not provide date of the publication. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CAR 1.97(e). See MPEP § 609 C(1).

Withdrawn Claim Rejections

6. The new matter rejection of claims 25-29 has been withdrawn in view of the amendment to the claims.
7. The obviousness type double patenting rejection of claims 25-29 has been withdrawn in view of the Terminal disclaimers filed on 9/25/03.

New rejections necessitated by the Amendment

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 25-29 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over either US Patent 4,404,289 (MASUDA et al) or US Patent 4,405,711 (MASUDA et al).

Masuda et al (the '289 patent) disclose methods for immunochemical measurement of trace component. The reference discloses that the antigen or antibody (refers to protein or component of the instant claims) labeled with spectral sensitizers such as cyanine dyes of formula C (i.e., see column 10) (refers to the water soluble dye of the instant claims). The reference discloses that the disclosed spectral sensitizers are particularly advantageous as the labeling substances since these dyes are excellent in binding to the trace components such as antigen or antibody. The reference discloses the cyanine dye of formula C in columns 11-13. The reference discloses that the cyanine dye of formula C and water (refers to the water soluble dye of the instant claim) is used in labeling insulin (a protein) (e.g., example 1), lysozyme (e.g., example 2). The reference discloses that the insulin labeled with spectral sensitizer (I) has absorption spectrum of 660 nm (within the '400-900 nm range' of absorption of the instant claim dye). The reference discloses that the amount of spectral sensitizer used for labeling varies depending upon the kind of substances to be labeled, but is generally in a molar ratio of 1/100 to 100 moles per 1 mole of antigen or antibody.

Masuda et al (the '711 patent) discloses a method of assay for a trace component such as antigen, antibody or enzyme utilizing immunochemical reaction or enzyme reaction in combination with photographic detection system comprising optical density. The reference

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discloses that the spectral sensitizer employed for labeling a trace component such as antigen or antibody or synthetic substrate, include cyanine dyes (i.e., see column 10) (refers to the water soluble dye of the instant claims).

Masuda et al (the '289 patent and the '711 patent) teach cyanine dyes and the use of the dyes to label antigen or antibody or proteins. Masuda et al do not teach that the 'individual dye molecule has an average molar extinction coefficient of at least 50,000 liters per mole centimeter, an average quantum yield of at least 5 percent...' The claimed invention further differs from the prior art teachings only by the recitation of properties of the cyanine dyes (individual dye molecule has an average molar extinction coefficient of at least 50,000 liters per mole centimeter, an average quantum yield of at least 5 percent). However Masuda et al teach cyanine dyes which read on the instant claimed dyes. The reference teaches the same dyes of the instant claim composition, and the dye has the absorption range within the claimed range of 400-900 nm. Thus the claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific properties of the instant composition versus the reference composition. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed composition has a different dye from the one taught by prior art and to establish the patentable differences. See *in re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922 (PTO Bd. Pat. App. & Int. 1989).

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12. Claims 25-28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Waggoner et al (Biophysical Journal, vol. 33, 1981, page 292a).

Waggoner et al disclose that the reactive sulfhydryl group on the F1 region of cattle rhodopsin (chromoprotein) (refers to the instant claim component) has been covalently labeled with a cyanine dye (refers to the instant claim dye). The absorption of the dye at 660 nm is sensitive to conformational changes of rhodopsin that occur following a short and intense light flash. The reference discloses labeled detergent solution of rhodopsin (refers to soluble dye of the instant claims).

Waggoner et al do not teach that the 'individual dye molecule has an average molar extinction coefficient of at least 50,000 liters per mole centimeter, an average quantum yield of at least 5 percent...' The claimed invention further differs from the prior art teachings only by the recitation of properties of the cyanine dyes (individual dye molecule has an average molar extinction coefficient of at least 50,000 liters per mole centimeter, an average quantum yield of at least 5 percent). However Waggoner et al teach cyanine dyes which read on the instant claimed dyes. The reference teaches the same dyes of the instant claim composition, and the dye has the absorption range within the claimed range of 400-900 nm (the absorption of the reference dye is at 660 nm, within the claimed range). Thus the claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific properties of the instant composition versus the reference composition. In the absence of evidence to the contrary, the burden is upon the

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applicant to prove that the claimed composition has a different dye from the one taught by prior art and to establish the patentable differences. See *in re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922 (PTO Bd. Pat. App. & Int. 1989).

13. Claims 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 3,148,187 (Heseltine et al) and US Patent 4,404,289 (Masuda et al).

US Patent 3,148,187 (Heseltine et al) teaches sulfonated cyanine and merocyanine dyes. The reference teaches nuclear sulfonated dyes. The reference teaches the nuclear sulfo-substituted dyes of the invention include cyanine dyes of formula I. The reference teaches the methods of sulfonating the cyanine dyes. The reference teaches that the sulfonated dyes are valuable for use in photography because of their good solubility in water (see column 6). The reference teaches the soluble dyes are prepared by direct nuclear sulfo nation of cyanine dyes. The reference teaches that the dyes prepared by the method are distinguished from the prior art dyes by having at least one sulfo group attaches to a nuclear carbon atom rather than a nitrogen atom in the heterocyclic ring (i.e., see column 6). The reference sulfonated cyanine dyes read on the cyanine dye of claim 13. The claimed invention differs from the prior art teachings by reciting that the component has at least one amino or hydroxy group which reacts with the cyanine dye.

The claimed invention differs from the prior art teachings by reciting 'dye labeled component.' US Patent 3,148,187 (Heseltine et al) teaches cyanine dyes useful in photography. The reference recites water soluble cyanine dyes. The reference does not teach that the cyanine dyes are used in labeling biological compounds. However Masuda et al teach methods for

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immunochemical measurement of trace component. The reference teaches that the antigen or antibody (refers to protein or component of the instant claims) labeled with spectral sensitizers such as cyanine dyes of formula C (i.e., see column 10) (refers to the water soluble dye of the instant claims). The reference teaches that the disclosed spectral sensitizers are particularly advantageous as the labeling substances since these dyes are excellent in binding to the trace components such as antigen or antibody. The reference teaches cyanine dye of formula C in columns 11-13. The reference discloses that the cyanine dye of formula C and water (refers to the water soluble dye of the instant claim) is used in labeling insulin (a protein) (e.g., example 1), lysozyme (e.g., example 2). The reference teaches that the insulin labeled with spectral sensitizer (I) has absorption spectrum of 660 nm (within the '400-900 nm range' of absorption of the instant claim dye). The reference discloses that the amount of spectral sensitizer used for labeling varies depending upon the kind of substances to be labeled, but is generally in a molar ratio of 1/100 to 100 moles per 1 mole of antigen or antibody.

Thus it would have been obvious to one skilled in the art to use the water soluble cyanine dyes taught by the reference US Patent 3,148,187 (Heseltine et al) or Masuda et al with the method of labeling antigen or antibody taught by US Patent 4,404,289 because US Patent 3,148,187 (Heseltine et al) teaches the advantages of the water soluble sulfonated cyanine dyes and the '289 teaches the advantages of the use of spectral sensitizers in labeling the antigen or antibody. A person skilled in the art would have been motivated to obtain the cyanine dye labeled compounds such that labeled compounds are useful in diagnostic assays which would enable one to reduce the quantity of a testing sample required for improved detection sensitivity and thus enables multiple test samples.

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Response to Arguments

14. Applicant's arguments, see the response filed on 9/25/03, with respect to the rejection(s) of claim(s) 25-29 under 35 U.S.C. 112 first paragraph have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the amendment filed on 9/25/03 and 11/7/03.

Conclusion

15. No claims are allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

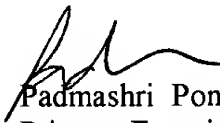
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 703-305-3884. The examiner is on Flex Schedule and can normally be reached from Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.


Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

Pp
21 January 2004